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ABSTRACT

The paper presents a summary of the findings from a 1982 conference held by the National Institutes of Health on the issue of diets and hyperactivity. Six questions are addressed, touching on the nature of hyperactivity and its quantifiable measurement, defined diets, empirical evidence regarding the effects of these diets on hyperactivity, possible biological explanations to support an effect of defined diets on hyperactivity, circumstances for implementing diets, and directions for future research. Among conclusions reached by panel members (who included representatives of biomedical research, psychiatry, pharmacy, education, and environmental law) were that the cluster of symptoms known as hyperactivity does not represent a single disease; research evidence is not adequate; and a defined diet should not be initiated until thorough diagnosis and evaluation and a consideration of all options have taken place. Further research is advocated in the areas of epidemiologic studies, diet, psychosocial/behavioral issues, and animal studies. (CL)

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# Defined Diets and Childhood Hyperactivity

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National Institutes of Health
Consensus Development
Conference Summary
Volume 4 Number 3

A Consensus Development Conference was held at the National Institutes of Health on January 13, 14, and 15, 1982, to seek positions on issues involving defined diets and childhood hyperactivity.

At NIH, Consensus Development Conferences bring together biomedical investigators, practicing physicians, consumers, and health advocacy groups to provide a scientific assessment of technologies, including drugs, devices, and procedures, and to seek agreement on their safety and effectiveness.

On the first two days of the meeting, experts presented evidence to a Consensus Development Panel and members of the audience on the following key questions:

1. What constitutes the hyperactivity syndrome in children? Is it a single disease or a cluster of diseases? Can it be graded or scaled in quantifiable variables such as attention span, learning ability, and social adjustment and by whom (teachers, parents, medical personnel)?
2. What are the defined diets?
3. Is there empirical evidence for an effect of these diets on hyperactivity?
4. Is there any biological explanation to support an effect of defined diets on hyperactivity?
5. If defined diets are effective, how and under what circumstances should they be employed?
6. What are the directions for research?

Panel members were drawn from the lay public, biomedical research, pediatrics, nutrition, immunology and allergy, clinical pharmacy, psychiatry and behavioral sciences, genetics, education, epidemiology, biostatistics, environmental health, and law, all relevant to a discussion of diets and childhood hyperactivity.

The National Institutes of Health urges that this summary statement be posted, duplicated, and distributed to interested staff.

## Introduction

Childhood hyperactivity, officially termed the "attention deficit disorder with hyperactivity," but variously referred to as "hyperkinetic reaction of childhood," "hyperkinetic syndrome," "hyperactive child syndrome," "minimal brain damage," "minimal brain dysfunction," "minimal cerebral dysfunction," "and minor cerebral dysfunction," is an important health concern affecting afflicted children, their families, and those around them. Traditional therapy for this condition has included behavior modification, educational techniques. psychotherapy, and pharmacotherapy—most prominently amphetamine-like medications.

The 1973 report by Feingold of clinical observations on the benefit of a diet free of salicylates and food additives on hyperactivity focused attention on this new treatment approach. The publication of the Feingold diet in book form came at a time of increasing public concern about environmental pollution and a desire for full knowledge of all additives found in prepared food and the presence of such sub-

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stances in the diet. These trends, along with a heightened aversion to habitual use of medication, an increase in awareness of the possible causative role of nutritional factors in diseases of many types, a desire for self-involvement in health care, and the frustration encountered in managing childhood hyperactivity, led to the widespread experimentation with the Feingold regimen and other defined diets.

Some controlled, double-blind studies indicate that these diets are only occasionally efficacious. Apparent discrepancies between some clinical impressions of efficacy and much of the available scientific evidence prompted the scheduling of this Consensus Development Conference.

**1.**
**What constitutes the hyperactivity syndrome in children? Is it a single disease or a cluster of diseases? Can it be graded or scaled in quantifiable variables such as attention span, learning ability, and social adjustment and by whom (teachers, parents, medical personnel)?**

Innumerable definitions have been offered for the hyperactivity syndrome in children. The latest of these, in *Diagnostic and Statistical Manual III (DSM III)* (the American Psychiatric Association), delineates the varied symptomatology in this behavioral syndrome. According to *DSM III*, "the essential features are signs of developmentally inappropriate inattention, impulsivity, and hyperactivity." Other diagnostic qualifiers include onset prior to the age of 7, a duration of no less than 6 months, and a proven absence of mental illness or mental retardation.

The cluster of symptoms does not represent a single disease, nor is it likely that the etiology is singular; rather, the syndrome may be secondary to (1) organic factors such as trauma, infection, lead intoxication, and significant perinatal hypoxia; (2) predisposing genetic (familial) factors; or (3) psychosocial factors such as anxiety, inadequate parenting, and environmental stresses. In most cases the etiology is unknown and may be the result of synergism of several of the predisposing factors listed above.

The diagnostic process optimally includes the participation of parents, medical personnel, teachers, psychologists, and social workers. Several useful tests and rating scales for quantification of important variables such as attention span, learning ability, and social adjustment are available to those involved in the process; however, a need for more concise assessment tools is apparent. The recent development of electronic devices for measuring motor activity may prove helpful in providing a more refined quantitation of attention span and hyperactivity.

If progress is to continue in treatment of hyperactivity, it will be necessary to improve accuracy in diagnosis and to develop objective methods to monitor the effect of each approach to treatment and the course of the patient.

**2.**
**What are the defined diets?**

The term "defined diets" includes several dietary modifications. The basic diet described by Feingold eliminated two groups of foods: Group I consists of almonds, cucumbers, tomatoes, berries, apples, oranges, and several other fruits. These were excluded because of high levels of naturally occurring salicylates. Group II includes foods known or thought to contain artificial colors and flavors (most of these latter foods were perceived by the public as "processed"). This category was largely selected on the basis of ingredient (including additive) labeling and standards of food identity. With the exception of BHT (butylated hydroxytoluene), foods containing preservatives were not excluded from the original Feingold diet. No restrictions were placed on homemade sweets, but commercially prepared desserts and other foods to which relatively high amounts of sucrose had been added were usually disallowed on the basis of their content of artificial color and/or flavors.

Defined diets came to include certain modifications of the Feingold diet. Excluded from experimental diets were foods containing BHA (butylated hydroxyanisole) and sodium benzoate; certain Group I foods containing artificial preservatives were not excluded. Another modification appears to have occurred in some home settings. Parents of children whose behavior improved on dietary modification explained

that the Feingold diet was, at times, further restricted by excluding milk, normally a permitted food, or on the basis of adverse personal experiences with individual dietary items.

Other types of studies and therapeutic trials used defined diets in which nonnutritive additives were excluded, as well as foods such as corn, wheat, and milk regardless of additive content. After a preliminary trial, this type of defined diet was then modified by reintroducing individual food items one at a time and evaluating the effects of such additions upon the subject's behavior.

**3.**
**Is there empirical evidence for an effect of these diets on hyperactivity?**

Parents and other observers have frequently reported dramatic improvements in many hyperactive children during uncontrolled trials of various defined diets. However, such dramatic improvements were not observed in a number of controlled trials reported at the conference.

While differences and inadequacies in the design of the controlled trials make analysis difficult, these studies did indicate a limited positive association between "the defined diets" and a decrease in hyperactivity. Some hyperactive children demonstrated less evidence of hyperactivity on defined diets, or modifications thereof, than on an appropriate control diet. Such decreases involved only a small proportion of patients; furthermore, the decreases in hyperactivity were not observed consistently. Studies also indicated that some hyperactive children on a defined diet experienced an increase in hyperactivity when given moderate doses of artificial food dyes, and did not experience similar increases after receiving a placebo. This increase in hyperactivity was also experienced by only a small group of patients, and the increase was not consistently reported by teachers, parents, and other observers.

Clinical observations also indicated that children who were successfully managed on a defined diet experienced hyperactivity after dietary noncompliance. Controlled challenge studies have primarily involved the administration of food dyes to children, but have not included other food flavors or preservatives that are allegedly implicated in the causation of hyperactivity. Therefore, these controlled challenge studies do not appear to have addressed adequately the role of diet in hyperactivity.

**4.**
**Is there any biological explanation to support an effect of defined diets on hyperactivity?**

Only one specific biological explanation has been proposed—that the food dye erythrosine (FDC Red No. 3) inhibits neurotransmitter uptake. Experimental studies first suggested that Red No. 3 could inhibit the uptake of dopamine and other neurotransmitters *in vitro*. If true, this observation presented a mechanism by which this food additive could affect behavior. However, more recent studies suggested that this effect of Red No. 3 was the result of nonspecific interactions, and these studies raised doubts about whether Red No. 3 would affect the behavior of the intact organism. In support of this latter idea, data from three groups using the laboratory rat found that Red No. 3 caused no increase in activity or had effects only at near lethal doses. Additionally, one study in children found that the minor behavioral changes apparently caused by challenge with a mixture of food colors were a result of food colors other than Red. No. 3.

Despite these negative preliminary data, it was recognized that further research, especially pharmacokinetic studies, were needed before these questions could be answered conclusively about Red No. 3 or other dietary agents. Moreover, other explanations of why a defined diet lacking food dyes, flavorings, preservatives, salicylates, and major food antigens may be beneficial can only be suggested. Direct toxic effects, idiosyncratic reactions to such agents, and hypersensitivity (allergic) responses (both IgE-mediated and non-IgE-mediated) to food antigens also could cause the observed findings. This might be by direct effects on the central nervous system or by indirect effects on other systems. However, no direct evidence for the operation of these mechanisms in treated patients is available at this time.

Placebo effects and observer bias inherrent to any major therapeutic intervention (when not controlled by appropriate blinded procedures), may also account for some of the reported benefits.

**5.**
**If defined diets are effective, how and under what circumstances should they be employed?**

Case reports of a subset of responding patients presented to this panel by parents and physicians documented improvement in the hyperactive child's condition with the use of defined diet. Because insufficient evidence is available to permit identification beforehand of this small group of individuals who may respond and to determine under what circumstances they may derive benefits, the Panel cannot answer this question unequivocally.

The Panel believes the defined diets should not be universally used in the treatment of childhood hyperactivity at this time. However, the Panel recognizes that initiation of a trial of dietary treatment or continuation of a diet in patients whose families and physicians perceive benefits, may be warranted. A defined diet should not be initiated until thorough and appropriate evaluation of the children and their families and full consideration of all traditional therapeutic options (described in the Introduction) have taken place.

The ability to describe "defined diets" precisely and to ensure proper and effective clinical use, to measure compliance, and to design studies and compare the findings from one study to another depends upon making available to consumers and investigators food and food products that are completely labeled. The Panel understands that existing law does not require identifying on the label, completely and accurately, all ingredients in food. The Panel, therefore, recommends changes in the law to require the listing on labels of all ingredients of food and food products, and that this label include substances that may migrate from wrappers and containers that come in contact with foods.

The Panel also believes that special attention must be given to individual cultural, ethnic, and socioeconomic factors to ensure the proper implementation of the diet. Since the defined diets differ from traditional dietary patterns, it is the physician's responsibility to be specific and impart the knowledge and support that individual families need in implementing these diets.

**6.**
**What are the directions for research?**

The Panel identified a number of critical gaps in knowledge which affect interpretation of the results of dietary intervention in the management of the hyperactivity syndrome. These deficiencies include nonuniform diagnostic standards and inadequate information regarding the natural history of this syndrome, lack of availability of optimal measurement instruments (behavioral, cognitive, and other), and other significant limitations in the research study designs employed to date. In addition, the full potential of animal and in vitro studies for generating relevant biologic information has not been realized. Therefore, further research in each of these areas is needed to be able to conduct meaningful investigations of the potential benefits of dietary management of hyperactivity.

The following directions for further research are recommended:

- *Epidemiologic studies*—Including: the development of standardized working diagnostic criteria (essential for all research in this disorder), and possible neurophysiologic, biochemical, or other diagnostic "markers." Studies of the etiology and risk factors for the condition and delineation of its natural history are needed. Such studies should address possible genetic, developmental, and environmental factors which could both be causal and also serve as predictors of prognosis and should better define those afflicted children who may be likely to respond to a given therapy. Several of these goals require longitudinal prospective studies. For this purpose, it is recommended that existing defined populations and data sources be identified and employed whenever possible.

- *Psychosocial/behavioral*—The development and utilization of standardized instruments for the assessment of cognitive, attentional, and behavioral changes in patients receiving different modalities of therapy is essential. This may involve the adaptation of existing instruments or the development of new ones for these purposes. Investigations of family dynamics are essential for understanding the impact of both the disorder and the different modalities of therapy.

- *Diet*—Further dietary research is needed with improved study design, including particular attention to certain features such as adequate sample size, explicit criteria for selection of subjects, ensuring and monitoring compliance, precise definition of the diet or dietary agent being tested, and consideration of synergistic effects of simultaneous exposure to additional dietary and/or other agents. Randomized, double-blind trials with checks on the adequacy of the blinding and repetitive evaluations are needed. Moreover, studies are also needed of the possible adverse effects of dietary intervention, on both the patient and the family, and of both a biologic and a psychosocial nature. These types of studies are essential for risk-benefit assessments that should also be carried out for other nondietary options of therapy.

- *Animal studies*—These studies offer an obvious opportunity for obtaining relevant biologic information. However, such studies should be conducted with particular attention to dosages of specific test substances, standardization of rigorously defined synthetic diets, routes of administration, and genetic factors. These studies should provide important information regarding the absorption, distribution, metabolism, and mechanism of action of the agents being tested and may be particularly relevant for human populations if appropriate behavioral endpoints in the animal model can be developed.

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*A bibliography on defined diets and childhood hyperactivity is available from the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205. This bibliography was prepared by the National Institute of Allergy and Infectious Diseases.*



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